510(k) Summary

JUN 2 0 2013

Aircast® VenaFlow® Elite System
510(k) Number K130722

Applicants Name:	DJO, LLC 1430 Decision Street Vista, Ca 92081
Contact Person:	Lorri Trotter Regulatory Affairs Specialist Phone: 760-734-3049 Fax: 760-734-5544 Email: lorri.trotter@djoglobal.com
Date Prepared:	March 15, 2013
Trade Name:	Aircast VenaFlow Elite System
Common/Usual Name:	Compressible Limb Sleeve Device
Classification Name:	Sleeve, Limb, Compressible (21 CFR 870.5800, Product Code JOW)
Regulatory Class:	Class II
Predicate Device(s):	Aircast VenaFlow Elite System (K122499)
Device Description:	The Aircast VenaFlow Elite System is a prescription only, intermittent pneumatic compression device designed to apply rapid inflation with graduated sequential compression to a patient's calf, thigh or foot for the purpose of assisting blood flow in the veins. This rapid inflation and graduated, sequential compression device accelerates venous velocity and enhances fibrinolysis. The Aircast VenaFlow Elite System provides two different modes for inflation. The system defaults to Standard Operation which inflates the cuffs one leg at a time, alternating between the two legs once every 30 seconds. The cuffs inflate within less than 0.5 seconds. The system has an alternate S Mode which inflates both cuffs at the same time, once every 60 seconds.

	The cuffs inflate in approximately 10 seconds. The Aircast VenaFlow Elite System provides the user with an option of battery operation in addition to operation from the mains power. The Aircast VenaFlow Elite System is easy to use and provides the user with several cuff type options: calf, thigh and foot as well as combined compression of any combination of two cuffs. The Aircast VenaFlow Elite System is available in two configurations. The CLINICAL configuration is for medical facilities and offers the full range of accessories including cuffs, varying tube lengths, optional battery and replacement kits. The HOME configuration is for home use and is provided with simplified patient instructions and offers a specific set of accessories limited to calf cuffs and tubing.
Intended Use:	The Aircast VenaFlow Elite System is an intermittent pneumatic compression device that is intended to apply intermittent application of pressure to a patient's calf, thigh or foot for the purpose of assisting blood in the veins. The Aircast VenaFlow Elite System is a prescription device for use in a clinical setting or in the home.
Technological Characteristics:	The modified device has the same technological characteristics as compared to predicate device Aircast VenaFlow Elite System (K122499)
Performance Data:	A Failure Modes and Effects Analysis (FMEA) was created to adequately assess the risks of the device. Known and potential hazards for operation of the Aircast VenaFlow Elite System were evaluated for risk and the severity of the failure effects to the user and probability of occurrence were categorized. A Human Factors and Usability Study was conducted to validate the usability of the Aircast VenaFlow Elite System in the home environment. The result of the Human Factors and Usability Study substantiates the acceptability of the risks identified during the risk assessment activities. The modified device meets Electrical Safety testing according

	to IEC 60601-1 and Electromagnetic Compatibility according to IEC 60601-1-2.
Conclusion:	Based on the performance testing and the supporting documentation, it can be concluded that the Aircast VenaFlow Elite System is safe, effective and substantially equivalent to the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

June 20, 2013

DJO, LLC
Lorri Trotter
1430 Decision Street
Vista, CA 92081-8553

Re: K130722
Trade/Device Name: Aircast VenaFlow Elite System
Regulation Number: 21 CFR 870.5800
Regulation Name: Compressible Limb Sleeve
Regulatory Class: Class II
Product Code: JOW
Dated: April 18, 2013
Received: April 23, 2013

Dear Lorri Trotter:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Bram D. Zuckerman -S

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K130722

Device Name: Aircast VenaFlow Elite System

Indications For Use:

Prophylaxis for Deep Vein Thrombosis (DVT) for use in a clinical setting or in the home.

Prescription Use X AND/OR Over-The-Counter Use
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Bram D. Zuckerman -S
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